Puma Biotechnology Reports Fourth Quarter and Full Year 2017 Financial Results

March 1, 2018

LOS ANGELES--(BUSINESS WIRE)--Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced financial results for the fourth quarter and year ended December 31, 2017. Unless otherwise stated, all comparisons are for the fourth quarter and full year 2017, compared to the fourth quarter and full year 2016.

On July 17, 2017, Puma Biotechnology received approval from the U.S. Food and Drug Administration (FDA) for NERLYNX® (neratinib) for the treatment of early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy, and the Company began shipment to wholesalers at the end of July 2017. The Company reported net revenue from initial sales of NERLYNX of approximately $20.1 million in the fourth quarter and $26.2 million for the full year 2017.

Based on accounting principles generally accepted in the United States (GAAP), Puma reported a net loss applicable to common stock of $64.1 million, or $1.71 per share, for the fourth quarter of 2017, compared to a net loss of $72.7 million, or $2.04 per share, for the fourth quarter of 2016. Net loss applicable to common stock for the full year 2017 was $292.0 million, or $7.85 per share, compared to $276.0 million, or $8.29 per share, for the full year 2016.

Non-GAAP adjusted net loss was $38.6 million, or $1.03 per share, for the fourth quarter of 2017, compared to non-GAAP adjusted net loss of $43.4 million, or $1.22 per share, for the fourth quarter of 2016. Non-GAAP adjusted net loss for the full year 2017 was $183.3 million, or $4.93 per share, compared to non-GAAP adjusted net loss of $158.8 million, or $4.77 per share, for the full year 2016. Non-GAAP adjusted net loss excludes stock-based compensation expense, which represents a significant portion of overall expense and has no impact on the cash position of the Company. For a reconciliation of GAAP net loss to non-GAAP adjusted net loss and GAAP net loss per share to non-GAAP adjusted net loss per share, please see the financial tables at the end of this news release.

Net cash used in operating activities for the fourth quarter of 2017 was $35.6 million. Net cash used in operating activities for the full year 2017 was $172.5 million. At December 31, 2017, Puma had cash and cash equivalents of $81.7 million, compared to cash and cash equivalents of $194.5 million and marketable securities of $35.0 million at December 31, 2016. In November 2017, Puma announced that it entered into a loan agreement with Silicon Valley Bank and Oxford Finance for a term loan of up to $100 million, subject to funding in two tranches. Puma received gross proceeds of $50 million from the first tranche of the credit facility upon closing on October 31, 2017.

Due to unanticipated delays by Puma surrounding certain disclosures related to tax and tax reform, Puma needs more time to complete its financial statements and to prepare its Form 10-K for the fiscal year ended December 31, 2017. As a result, Puma is not in a position to file its Form 10-K within the prescribed time period without unreasonable expense and effort. Puma expects that its Form 10-K will be filed within the 15 day period specified by Rule 12b-25(b)(2)(ii) of the Securities Exchange Act of 1934, as amended.

“With the FDA approval and successful launch of NERLYNX for extended adjuvant treatment of HER2-positive early stage breast cancer in the United States, 2017 was truly a milestone year for Puma Biotechnology,” said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. “Further, we presented results of our ongoing studies at major conferences, including our Phase III ExteNET study at the European Society for Medical Oncology 2017 Congress, our Phase II CONTROL study at the 2017 San Antonio Breast Cancer Symposium, and our Phase II SUMMIT study at the 2017 American Association for Cancer Research Annual Meeting.”

Mr. Auerbach added, “During 2018, we anticipate the following key milestones for Puma: (i) submitting for a re-assessment of the Marketing Authorisation Application for neratinib by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in the first quarter of 2018; (ii) reporting updated Phase I/II data from neratinib plus Kadcyla (T-DM1) in HER2-positive metastatic breast cancer trial in the second quarter of 2018; (iii) reporting data from a Phase III trial in third-line metastatic breast cancer patients in the first half of 2018; (iv) submitting neratinib for regulatory approval for extended adjuvant HER-2 positive early stage breast cancer in certain markets outside of the United States in the second half of 2018; (v) reporting additional data from the Phase II CONTROL trial in the fourth quarter of 2018; and (vi) reporting Phase II data from the SUMMIT basket trial of neratinib in patients with HER2 mutations in the second half of 2018.”

Product Revenue

Net revenue consists of sales of NERLYNX, Puma’s first and only commercial product to date. The FDA approved NERLYNX in July 2017 and the Company commenced shipment to wholesalers in late July. For the three and twelve months ended December 31, 2017, net revenue was approximately $20.1 million and $26.2 million, respectively.

Operating Expenses

Operating expenses were $85.2 million for the fourth quarter of 2017, compared to $72.9 million for the fourth quarter of 2016. Operating expenses were $320.1 million for the full year 2017 compared to $276.6 million for the full year 2016.

Cost of Sales:

Cost of sales was $4.1 million for the fourth quarter and $5.6 million for the twelve months ended December 31, 2017. The Company had no product sales prior to the third quarter of 2017.

Selling, General and Administrative Expenses:

Selling, general and administrative expenses were $30.9 million for the fourth quarter of 2017, compared to general and administrative expenses of $16.5 million for the fourth quarter of 2016. Selling general and administrative expenses for the full year 2017 were $106.7 million, compared to general and administrative expenses of $53.8 million for the full year 2016. The increase of approximately $52.9 million during the full year 2017 compared to the same period in 2016 resulted primarily from increases of approximately $16.1 million for the hiring and training of our commercial sales force, $18.5 million in external costs for the commercial launch of NERLYNX, $7.3 million in legal expenses, $4.6 million in stock-based compensation, and approximately $5.0 million in other internal expenses, such as increased headcount, software and depreciation expenses.

Research and Development Expenses:

Research and development expenses were $50.2 million for the fourth quarter of 2017, compared to $56.4 million for the fourth quarter of 2016. Research and development expenses for the full year 2017 were $207.8 million, compared to $222.8 million for the full year 2016. The decrease of approximately $15.0 million during the full year 2017 compared to the same period in 2016 resulted primarily from decreases of approximately $13.1 million in stock-based compensation and $6.8 million in manufacturing costs related to preparation of the commercial launch of NERLYNX, offset by increases of approximately $1.0 million in clinical study-related expense and $3.9 million in other internal expenses, such as increased headcount, travel and software.

Conference Call

Puma Biotechnology will host a conference call to report its fourth quarter and full year 2017 financial results and provide an update on the company's business and outlook at 1:30 p.m. PST/4:30 p.m. EST on Thursday, March 1, 2018. The call may be accessed by dialing 1-877-709-8150 (domestic) or 1-201-689-8354 (international) at least 10 minutes prior to the start of the call and referencing the “Puma Biotechnology Conference Call.” A live webcast of the conference call and presentation slides may be accessed on the Investors section of the Puma Biotechnology website at http://www.pumabiotechnology.com/. A replay of the call will be available approximately one hour after completion of the call and will be archived on the company's website for 90 days.

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses the global development and commercialization rights to three drug candidates — PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. NERLYNX® (neratinib, oral) is approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4. Currently, the Company is primarily focused on the commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX has clinical application in the potential treatment of several other cancers that over-express or have a mutation in HER2.

Further information about Puma Biotechnology may be found at www.pumabiotechnology.com.

IMPORTANT SAFETY INFORMATION

NERLYNX ® (neratinib) tablets, for oral use

INDICATIONS AND USAGE: NERLYNX is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS:

- **Diarrhea:** Aggressively manage diarrhea occurring despite recommended prophylaxis with additional antidiarrheals, fluids, and electrolytes as clinically indicated. Withhold NERLYNX in patients experiencing severe and/or persistent diarrhea. Permanently discontinue NERLYNX in patients experiencing Grade 4 diarrhea or Grade ≥ 2 diarrhea that occurs after maximal dose reduction.

- **Hepatotoxicity:** Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold NERLYNX in patients experiencing Grade 3 liver abnormalities and permanently discontinue

NERLYNX in patients experiencing Grade 4 liver abnormalities.

- **Embryo-Fetal Toxicity:** NERLYNX can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS: The most common adverse reactions (≥ 5%) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased and urinary tract infection.

To report SUSPECTED ADVERSE REACTIONS, contact Puma Biotechnology, Inc. at 1-844-NERLYNX (1-844-637-5969) and www.NERLYNX.com or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch* .

DRUG INTERACTIONS:

- Gastric acid reducing agents: Avoid concomitant use with proton pump inhibitors (PPI) and H2-receptor antagonists. Separate NERLYNX by 3 hours after antacid dosing.
- Strong or moderate CYP3A4 inhibitors: Avoid concomitant use.
- Strong or moderate CYP3A4 inducers: Avoid concomitant use.
- P-glycoprotein (P-gp) substrates: Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX.

USE IN SPECIFIC POPULATIONS:

- **Lactation:** Advise women not to breastfeed.

Please see Full Prescribing Information for additional safety information.

Forward-Looking Statements

This press release and the webcast of the presentation contain forward-looking statements, including statements regarding the benefits of NERLYNX and neratinib, the Company's clinical trials and the announcement of data relative to those trials. All forward-looking statements involve risks and uncertainties that could cause the Company's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, the risk factors disclosed in the periodic and current reports filed by the Company with the Securities and Exchange Commission from time to time, including the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company assumes no obligation to update these forward-looking statements, except as required by law.

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions except share and per share data)

	Three Months Ended December 31, (Unaudited)		Twelve Months Ended December 31, (Unaudited)	
	2017	2016	2017	2016
Revenue, net	$ 20.1	$ —	$ 26.2	$ —
License revenue	1.5	—	1.5	—
Total revenue	21.6	—	27.7	—
Operating expenses:				
Cost of sales	4.1	—	5.6	—
General and administrative	30.9	16.5	106.7	53.8
Research and development	50.2	56.4	207.8	222.8
Totals	85.2	72.9	320.1	276.6
Loss from operations	(63.6)	(72.9)	(292.4)	(276.6)
Other income (expenses):				
Interest income	0.2	0.3	1.2	1.0
Interest expense	(0.7)	—	(0.7)	—
Other income (expense)	-	(0.1)	(0.1)	(0.4)

Totals	(0.5)	0.2	0.4	0.6
Net loss	$ (64.1)	$ (72.7)	$ (292.0)	$ (276.0)
Net loss per common share—basic and diluted	$ (1.71)	$ (2.04)	$ (7.85)	$ (8.29)
Weighted-average common shares outstanding—basic and diluted	37,534,410	35,694,193	37,169,678	33,295,114

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
LIQUIDITY AND CAPITAL RESOURCES
(in millions)

	December 31, 2017 (unaudited)	December 31, 2016 (unaudited)
Cash and cash equivalents	$ 81.7	$ 194.5
Marketable securities	—	35.0
Working capital	48.1	199.0
Stockholders' equity	53.3	209.8

	Twelve Months Ended December 31, 2017 (unaudited)	Twelve Months Ended December 31, 2016 (unaudited)
Cash provided by (used in):		
Operating activities	$ (172.5)	$ (141.7)
Investing activities	(15.4)	142.2
Financing activities	75.1	162.4
Increase (decrease) in cash and cash equivalents	$ (112.8)	$ 162.9

Non-GAAP Financial Measures

In addition to operating results as calculated in accordance with generally accepted accounting principles, or GAAP, the Company uses certain non-GAAP financial measures when planning, monitoring, and evaluating operational performance. The following table presents the Company’s net loss and net loss per share calculated in accordance with GAAP and as adjusted to remove the impact of employee stock-based compensation. For the three and twelve months ended December 31, 2017, stock-based compensation represented approximately 39.8% and 37.2% of net loss, respectively. Although net loss is important to measure financial performance, the Company currently places an emphasis on cash burn and, more specifically, cash used in operations. Stock-based compensation appears in GAAP net loss but is removed from net loss to arrive at cash used in operations on the statement of cash flows. Due to its noncash nature, the Company believes these non-GAAP measures enhance understanding of financial performance, are more indicative of operational performance and facilitate a better comparison among fiscal periods. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures.

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARY
Reconciliation of GAAP Net Loss to Non-GAAP Adjusted Net Loss and GAAP Net Loss Per Share to Non-GAAP Adjusted Net Loss Per Share
(in millions except share and per share data)
(Unaudited)

	Three Months Ended December 31,	
	2017	2016
GAAP net loss	$ (64.1)	$ (72.7)
Adjustments:		
Stock-based compensation -		

General and administrative	8.2	6.9	(1)
Research and development	17.3	22.4	(2)
Non-GAAP adjusted net loss	$ (38.6)	$ (43.4)	
GAAP net loss per share - basic and diluted	$ (1.71)	$ (2.04)	
Adjustment to net loss (as detailed above)	0.68	0.82	
Non-GAAP adjusted net loss per share	$ (1.03)	$ (1.22)	(3)

	Twelve Months Ended December 31,		
	2017	**2016**	
GAAP net loss	$ (292.0)	$ (276.0)	
Adjustments:			
Stock-based compensation -			
General and administrative	31.2	26.6	(1)
Research and development	77.5	90.6	(2)
Non-GAAP adjusted net loss	$ (183.3)	$ (158.8)	
GAAP net loss per share - basic and diluted	$ (7.85)	$ (8.29)	
Adjustment to net loss (as detailed above)	2.92	3.52	
Non-GAAP adjusted net loss per share	$ (4.93)	$ (4.77)	(4)

(1) To reflect a non-cash charge to operating expense for General and Administrative stock-based compensation.

(2) To reflect a non-cash charge to operating expense for Research and Development stock-based compensation.

(3) Non-GAAP adjusted net loss per share was calculated based on 37,534,410 and 35,694,193 weighted average common shares outstanding for the three months ended December 31, 2017 and 2016, respectively.

(4) Non-GAAP adjusted net loss per share was calculated based on 37,169,678 and 33,295,114 weighted average common shares outstanding for the twelve months ended December 31, 2017 and 2016, respectively.

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